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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,813	03/06/2002	Kelly Huang	JBP-581	8501

7590 09/26/2005

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EXAMINER
NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/091,813	HUANG ET AL.	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *7 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-16 and 18-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7-13-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-36 are pending.

2. Claims 7 and 17 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim, for reasons set forth in the Paper mailed 3-11-05. Applicant timely traversed the restriction (election) requirement in the reply filed on 12-10-04.

3. The claims being examined in the current office action are claims 1-6, 8-16 and 18-36.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-6, 8-16, 18-20 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (reference AL submitted in IDS received 3-6-02) in view of Perkins et al., 1997, (reference AG submitted in the IDS received 3-6-02), all of record for reasons set forth in the Paper mailed 3-11-05.

It is noted that claim 22 is included in the rejection as Reilly et al., teaches normalizing the eicosanoid levels by measuring protein levels in the skin secretions, as was previously stated in the Office action mailed 3-11-05.

7. Claims 11 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al., in view of Perkins et al., as applied to claim 11 above, and further in view of Mueller-Decker (reference AH on the IDS submitted 3-6-02) all of record for reasons set forth in the Paper mailed 3-11-05.

8. Claims 23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al. (reference AL submitted in IDS received 3-6-02) in view of Perkins et al., 1997, (reference AG submitted in the IDS received 3-6-02) and US Patent 4,281,061, all of record for reasons set forth in the Paper mailed 3-11-05.

Applicant's arguments filed 7-13-05 have been fully considered but are not found persuasive.

Applicant argues that Perkins does not teach measuring eicosanoid levels with Sebutape or provides motivation to use Sebutape to detect eicosanoid levels.

However, Perkins does teach that Sebutape can easily be applied in a clinical setting on any type of patient and that Sebutape was able to assess inflammatory changes in skin even in the absence of visible clinical irritation. Motivation for the use of Sebutape to detect skin irritation in general is provided by Perkins et al., since it can detect skin irritation in the absence of visible clinical irritation and can easily be applied in a clinical setting whether on infants, adults or geriatric adults. Why one of skill in the art would detect skin irritation by detecting eicosanoids and IL-1alpha is provided by Reilly et al.

Applicant argues there is no expectation that Sebutape would be successfully used to replace the suction blister method taught by Reilly et al.

Reference AB on the IDS submitted by Applicant on 3-6-02, clearly teaches how Sebutape works, as both a microporous film and adhesive patch. Since Sebutape detected levels of IL-1 alpha at 10pg/ml (see Perkins et al) and the PGE2 levels in irritated skin were at least at

that level (see Table 1, page 188 in Reilly et al.) one of skill in the art would readily expect that using Sebutape would be able to detect quantifiable amounts of PGE2 in skin.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-10 stand rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Applicant's arguments filed 7-13-05 have been fully considered but are not found persuasive.

Applicant argues it is not an essential step to apply an irritant to practice the method.

How would one know what they are testing for unless either an irritant was applied or it was previously known a patient's skin had been exposed to an irritant.

11. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

September 20, 2005